K000607

MAY 1 5 2000

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS FOR SOLO-CARE™ Brand HARD SOLUTION

1. **Submitter Information**

CIBA Vision Corporation
11460 Johns Creek Parkway
Duluth, Georgia 30097
Contact Person: Steven Dowdley
Telephone No. 678-415-3897

2. **Device Name**

Classification Name: Rigid Gas Permeable / PMMA Contact Lens Solution
Proprietary Name: SOLO-CARE™ Brand HARD SOLUTION

3. **Predicate Devices**

Currently marketed SOLOCare™ Brand HARD SOLUTION with a 4-hour regimen soak time was selected as the predicate devices for demonstrating substantial equivalence with SOLOCare Brand HARD SOLUTION with a 10 minute soak regimen. This product was selected because the formulation and indications for use are identical to the device proposed in this submission.

4. **Description of the Devices**

SOLO-Care ™ HARD Solution is a sterile aqueous solution containing hydroxyethylcellulose, tris amino, sodium chloride, disodium edetate, poloxamer 407, polyoxyethylene polyoxpropylene block copolymer, and is preserved polyhexanide 0.0002%. SOLO-Care ™ HARD Solution contains multiple active ingredients in sufficient concentration to perform the function of daily cleaning, rinsing disinfecting, and conditioning rigid gas permeable and hard contact lenses as recommended by an eye care practitioner.

5. **Indications for Use**

SOLO-Care ™ Hard Solution is indicated for use in daily cleaning, rinsing, chemical (not heat) disinfecting and conditioning of fluoro silicone acrylate, silicone acrylate and hard (PMMA) contact lenses as recommended by your eye care practitioner.

6. **Description of Safety and Substantial Equivalence**

A series of pre-clinical studies have been completed to demonstrate the safety and effectiveness of SOLO-Care Brand HARD Solution.

Preclinical Testing

Cleaning Effectiveness – Critical Micelle Results demonstrated that the surfactant concentration is formulated in SOLOCare Hard Solution at sufficiently high levels to maintain its activity for cleaning and detergency. This study was previously submitted and reviewed under K993949.

Contact Wetting Angle

Dynamic contact angle analysis indicated that the SOLO-care Hard Solution is statistically equivalent to predicate solution Boston Simplicity in terms of surface wettability of the lens. This study was previously submitted and reviewed under K993949.

Solution Compatibility

Compatibility testing of SOLO-care HARD with CAB, silicon acrylate and fluorsilicone acrylate lens materials was conducted to demonstrate compatible with various material types. The study showed that

after 30 cycles all parameters were still within the ANSI/ISO reference range for rigid gas permeable lenses for both solutions. In addition, there was no change in the cosmetic appearance of the lenses. This study was previously submitted and reviewed under K993949.

Stability (chemical and microbiological)

Shelf life for SOLO-Care HARD Solution has been demonstrated on 3 lots of product filled in white polypropylene bottles. Chemical stability testing was conducted at 4°C, 25°C, 30°C and 40°C on pH, osmolarity, viscosity, appearance and active ingredients. Based on the data collected, the trends observed and the estimated calculations of the accelerated test samples the shelf life for SOLO-care HARD Solution is 24 months. This study was previously submitted and reviewed under K993949.

Preservative Effectiveness

Studies were performed to evaluate the preservative effectiveness of SOLOCare HARD Solution. The results demonstrate that SOLO-Care Hard meets the requirements of the ISO/DIS 14730 Preservative Effectiveness Test against the panel organisms tested. This study was previously submitted and reviewed under K993949.

Disinfection Efficacy

The Stand-Alone Test was performed in accordance with ISO/CD 14729.3 (12/3/97version) and the FDA Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products, May 1997. Test samples of SOLO-Care HARD were analyzed at 2, 5, 7.2 and 10 minutes, with an additional 40-minute time period for C. albicans and F. soloni. The secondary criterion of the Stand Alone procedure was met while utilizing a 10 minute disinfection soak period, and qualified to be evaluated with the ISO Regimen Test.

The ISO Regimen Test was performed in accordance with ISO/CD 14729.3, version 12/3/97 to evaluate the microbial efficacy of the proposed 10 minute soak SOLO-Care regimen. The proposed SOLO-Care Multi-Purpose Solution regimen with a 10-minute disinfection soak period met the Regimen Test criteria as set forth in the ISO guidelines and FDA 510(k) Guidance Document for Contact Lens Care Products, May 1997. Both of these guidelines require that the average regimen recovery count is not greater than 10 cfu for each lens type/storage solution combination.

Toxicology Results

L929 Direct Contact Material Assay, L929 Agar Overlay Diffusion Assay, Growth Inhibition Test, and Ocular Irritation Test were conducted in accordance with and in conformance to applicable regulations. Results demonstrated that the solution and lenses treated with the solution did not cause a toxic response or increase ocular irritation. This study was previously submitted and reviewed under K993949.

Clinical Testing

Three clinical studies were used to evaluated SOLO-care Hard Solution. Overall 166 contact lens wearers were enrolled and were exposed to the test and control solution from a wearing period of 1 month to 6 months.

The data from the studies were examined using descriptive statistics, tests for normality, analysis of variance and/or t-tests where appropriate. Analysis of all data from the studies showed no that the test and control solutions were substantially equivalent. In addition, no additional safety concerns were raised regarding the test solution. These studies were previously submitted and reviewed under K993949.

7. **Substantial Equivalence**

SOLO-Care Brand HARD Solution is substantially equivalent to the predicate device. SOLO-Care Brand HARD Solution with a 10-minute disinfection soak regimen is substantially equivalent to SOLO-Care Brand Hard Solution with a 4-hour disinfection soak regimen.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 5 2000

Mr. Steven Dowdley, RAC
Senior Associate, Regulatory Affairs
CIBA Vision Corporation
11460 Johns Creek Parkway
Duluth, Georgia 30097-1556

Re: K000607
Trade Name: SOLO-Care™ Hard Solution
Regulatory Class: II
Product Code: 86 MRC
Dated: February 21, 2000
Received: February 23, 2000

Dear Mr. Dowdley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic, Ear, Nose and
Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

PART III. INDICATIONS FOR USE STATEMENT

510(k) Number: K000607

Device Name: SOLO-Care ™ Hard Solution

Indications for Use:
SOLO-Care ™ Hard Solution is indicated for use in daily cleaning, rinsing, chemical (not heat) disinfecting and conditioning of fluoro silicone acrylate, silicone acrylate and hard (PMMA) contact lenses as recommended by your eye care practitioner.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ☐ or Over-the-Counter: ☒

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K000607